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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,697	12/07/2001	Joyce Bedelia B. Santos	DIZ-1	5711

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/017,697	B. SANTOS ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *35-42* is/are allowed.

6)☒ Claim(s) *1-20, 22-24, 26, 28-33, 43-46* is/are rejected.

7)☒ Claim(s) *21,25,27 and 34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of declaration and exhibit and amendment and remarks filed 04/30/04, request for extension of time filed 06/04/04 and applicants' petition (regarding small entity versus large entity status) filed 06/10/04. It is noted that the petition was granted.

Claim Rejections - 35 USC § 102

1. Claims 1-4, 7, 8, 10, 11, 13, 15-19, 22-24, 26, 28-33 and 43-46 remain rejected under 35 U.S.C. 102(b) as being anticipated by White (US 5,431,916).

Applicants argue that White does not teach a liquid composition or the method of preparing a liquid composition and that White's composition is encapsulated and cannot thus be administered as a liquid. Applicants state that the examples in White disclose compositions and methods for the making of pharmaceuticals that are encapsulated within soft gelatin capsules. Applicants conclude that because White does not disclose each and every element of the claims 1 and 43 amended to say that the formulation is administered in liquid form, White cannot anticipate claims 1 and 43 and the claims dependent therefrom. Applicants then referred to the declaration by Dr. Kennie U. Dee.

2. Applicants' arguments filed 04/30/04 have been fully considered but they are not persuasive.

Applicants' attention is respectfully directed to White (US 5,431,916), column 8, lines 8-12, which states that "after the final mixture has been formulated, if a solution, the mixture should be buffered as close to neutral as possible without precipitating the pharmaceutically acceptable active. If the final composition is to be a suspension, the formulation should be buffered to a pH of about 7. Buffering to approximately a neutral pH stabilizes the ester

component of the invention reducing any tendency toward hydrolysis." Specifically in column 7, line 58, White states that if a solution is the desired form of the formulation, additional heat may be required to facilitate the dissolution of the pharmaceutically acceptable active. Solution is a liquid. Thus White discloses formulating the composition as a liquid or solution or suspension. Applicants' attention is also respectfully directed to examples I and V where it is stated "the resulting composition is suitable for oral administration, and encapsulation within soft gelatin shells." These examples disclose the preparation of solutions that can be administered orally or than can be encapsulated within soft gelatin capsules. The solutions/liquids of White are not only encapsulated in soft gelatin capsules as recognized by applicants, but the solutions/liquids can be administered as stated in examples I and V. Also, liquids and not solid formulations are put into the soft gelatin capsules.

Claim Rejections - 35 USC § 103

3. The rejection of claims 5, 6, 9, 12,14 and 20 under 35 U.S.C. 103(a) as being unpatentable over White (US 5,431,916) are addressed together. Here applicants referred back to the argument presented in the rejection under 35 USC 102(b) and to the declaration by DR. Kennie U. Dee. Furthermore, applicants state that the instant invention addresses the problem of "the unpleasant taste of a drug in a liquid format, where the liquid composition is a syrup, a ready-to-use suspension, or extemporaneously prepared liquid syrup or suspension such as, for example, dry powder for reconstitution with water, liquid concentrate for dilution, dispersible tablet or capsule" and that the taste-masked liquid composition has substantially reduced bitter taste and after taste. Applicants say the White's invention is an encapsulated composition and that all of the examples disclose pharmaceuticals encapsulated within soft gelatin capsules and

are thus not administered in liquid form. Applicants state that White's composition is a solid at room temperature and the composition is a bitter-tasting solid so that White does not teach or suggest a liquid composition or the taste masking thereof according to Dr. Kennie U Dee's declaration. Applicants also argue that White does not use polyethylene glycol to create a taste-masked composition but uses polyethylene glycol to solubilize certain pharmaceuticals. Applicants also state that White uses polyvinylpyrrolidone as a solubilizng or suspending agent in combination with tri-ester and not as a taste-masking agent. Applicants then argue that White does not teach or suggest claim 1 and therefore does not teach or suggest dependent claims 5, 6, 9, 14 and 20.

4. Applicants' arguments filed 04/30/04 have been fully considered but they are not persuasive.

Applicants' arguments center around the theme that White does not disclose a liquid composition. It was pointed out in the discussion above under 35 USC 102(b) that White discloses solution and suspensions in final form that are suitable for administration and encapsulation within soft gelatin capsules. White (column 8, lines 8-12) states "after the final mixture has been formulated, if a solution, the mixture should be buffered as close to neutral as possible without precipitating the pharmaceutically acceptable active. If the final composition is to be a suspension, the formulation should be buffered to a pH of about 7. Buffering to approximately a neutral pH stabilizes the ester component of the invention reducing any tendency toward hydrolysis." Specifically in column 7, line 58, White states that if a solution is the desired form of the formulation, additional heat may be required to facilitate the dissolution of the pharmaceutically acceptable active. Solution is a liquid. Thus White discloses

formulating the composition as a liquid or solution or suspension. Applicants' attention is also respectfully directed to examples I and V where it is stated "the resulting composition is suitable for oral administration, and encapsulation within soft gelatin shells." These examples disclose the preparation of solutions that can be administered orally or than can be encapsulated within soft gelatin capsules. The solutions/liquids of White are not only encapsulated in soft gelatin capsules as recognized by applicants, but the solutions/liquids can be administered as stated in examples I and V. Also, liquids and not solid formulations are put into the soft gelatin capsules.

Regarding polyethylene glycol, the polyethylene glycol cannot do one thing in one composition and do another in another composition. At best, what will happen is that the polyethylene glycol can perform both functions that applicants are according the glycol, that is, act as a taste-masking agent and also as a solubilizing agent. Applicants failed to provide the conditions in which the polyethylene glycol can act only as a taste-masking agent as applicants argue and the condition under which the polyethylene glycol will act as a solubilizing agent. Applicants claim a composition that comprises an unpleasant tasting drug, polyethylene glycol and polyvinylpyrrolidone (instant claim 1) and a method of preparing the composition (instant claims 43). A prior art's composition that meets the limitations as set forth would have the properties of that composition. The polyethylene glycol and polyvinylpyrrolidone of the prior art will accord to the composition of the prior art what the polyethylene glycol and the polyvinylpyrrolidone would do to the instant composition. Thus, in essence, because the composition of the prior art is the same as the instant composition, the bitter taste of the composition of the prior art would be masked. Applicants' composition comprises and does not exclude the presence of the tri-ester. If polyethylene glycol and polyvinylpyrrolidone are taste-

masking agents in the instant case, the polyethylene glycol and polyvinylpyrrolidone will also mask the taste of the bitter or unpleasant tasting drug. All the examples in White do not disclose solids, rather, the examples disclose solutions/suspensions/liquids and that these forms can be administered orally or encapsulated.

Dr. Kennie U. Dee's declaration:

Dr. Kennie U. Dee declares that White does not disclose a taste-masked liquid pharmaceutical composition but discloses encapsulated formulations that are not administered in liquid form.

On the contrary, White discloses solution or suspension formulations that are suitable for oral administration or encapsulation within soft gelatin capsules (column 10, lines 37 and 38; column 11, lines 38 and 39).

Dr. Kennie U. Dee declares that most of the examples in White are compositions and methods for manufacture of pharmaceuticals that are encapsulated within soft gelatin capsules.

On the contrary, the examples in White disclose preparation of solution/suspensions that can be administered orally or that can be encapsulated within soft gelatin capsules. It is noted that example II of White is the example that specifically discloses "using the resulting solution …to prepare soft gelatin capsules."

Dr. Kennie U. Dee declares that the compositions of White are bitter tasting and referred to exhibit 2.

The instant composition does not exclude the presence of tri-esters. The exhibit does not present a parallel example where the tri-ester of White is included in the instant composition. The tasting experiment thus focused on the composition of the prior art and not on the instant composition, which does not exclude tri-esters.

Dr. Kennie U. Dee declares that tri-esters are essential component in White and that the tri-esters are viscous liquids with a bitter taste.

Applicants' claimed invention does not exclude tri-esters in the instant composition. *Dr. Kennie U. Dee declares White does not disclose each and every element of claim 1 and 43 and their dependent claims.*

White discloses a composition that comprises tri-ester, polyvinylpyrrolidone, polyethylene glycol and a pharmaceutical agent that has a bitter taste. The instant claims do not exclude tri-esters from the composition and thus White discloses the limitations of claims 1 and 43.

Dr. Kennie U. Dee declares that Examiner's conclusion is incorrect because success cannot be reasonably expected by modifying White to arrive at the claimed invention in dependent claims 5, 6, 9, 12, 14 and 20 for the reasons that follow:

White does not disclose taste-masking or improving the taste of unpleasant tasting drug, Whites disclosure is limited to solvent systems with significant solvating properties that are able to dissolve relatively large quantities of pharmaceutical actives at high temperatures, Whites composition requires the inclusion of tri-esters that are bitter tasting that increases the amount of bitter tasting drugs and also increases the bitter taste of drugs that can be detected by the human tongue, and White's disclosure is strictly limited to compositions and methods for manufacture of pharmaceuticals that are encapsulated within soft gelatin capsules, White's disclosure is not sufficient to teach applicants' claimed taste-masked liquid pharmaceutical compositions.

White's disclosure is sufficient and teaches the instant claimed invention because White discloses the composition of the instant claims and because the claims fail to exclude the tri-esters of White, the composition White is the same as the instant composition. The study conducted failed to run a parallel composition with the composition of White where the trimester of White is included in the instant composition. The scope of applicants' composition is not met by the study as it excludes the tri-esters from the instant composition.

5. Claims 21, 25, 27 and 34 remain objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims because the prior art does not disclose composition comprising the drugs recited in said claims.

6. Claims 35-42 remain allowable because the prior art does not disclose the specific compositions recited therein.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BF

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